February 7, 2002

GlaxoSmithKline

GlaxoSmithKline
PO Box 13398
Five Moore Drive
Research Triangle Park
North Carolina 27709
Tel. 919 483 2100
www.gsk.com

Dockets Management Branch
Food and Drug Administration
HFA-305, Room 1-23
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Re: Docket Number 01D-0510
Comments on Draft Guidance for Industry on Integration of Dose-Counting Mechanisms Into MDI Drug Products

Dear Sir or Madam;

Enclosed please find comments from GlaxoSmithKline on the Draft Guidance for Industry on Integration of Dose-Counting Mechanisms Into MDI Drug Products. GlaxoSmith Kline thanks the agency for the opportunity to comment on the draft guidance. Comments are provided for consideration by the FDA. The specific comments are listed in order of appearance in the guidance, with general comments given first.

GlaxoSmithKline appreciates the opportunity to provide feedback and suggestions for this guidance. These comments are submitted in duplicate. If you have any questions about these submitted comments, please feel free to contact me at (919) 483-5857. Thank you for your consideration.

Sincerely,

Mary Faye S. Whisler

Mary Faye S. Whisler, Ph.D.
CMC Project Manager
US CMC Submissions

01D-0510

C 3

General Comments:

Throughout the guidance, phrases such as "beyond the recommended number of doses", "recommended number of actuations", and "end of its life" are used. Clarification of these terms would be helpful. Alternatively, the suggestion for replacement of these terms might be " the recommended label claim number of actuations".

Consideration should be given to using counting mechanisms other than by numerical count as the use of color indicating counters would be difficult for color-blind patients using the inhaler.

Specific Comments:

In Background, Section II., delete the last sentence of the second paragraph and replace it with the following sentences. "The addition of a dose counter to an individual MDI unit would allow the patient to reliably track the numbers of actuations used over the life span of the inhaler (i.e. until the label claim number of actuations have been used). This would prevent the patient from discarding an inhaler unnecessarily or using the product outside of the recommendations provided in the package insert."

Also, in Background (Section II), delete the third paragraph as this information has been discussed in the added sentence above or in the guidance text.

In Section III. C., Integration of Dose-Counting Mechanisms into MDI Products Under Development, Other Considerations, GSK suggests deletion of the recommendation for lock-out devices on maintenance medications, so as not to cause confusion for patients using multiple inhalers.

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